

REMARKS/ARGUMENTS

The above-noted amendments to the claims, cancellation of claims 2, 21, and 28, and the addition of new claims 32 and 33, are submitted in response to the official action dated June 12, 2006. The amendments to claim 1 primarily include incorporation of the limitations of prior claim 2 therein, and each of these amendments are supported in the specification. No new matter is included therein. Furthermore, since applicants respectfully submit that these amendments place each of these claims in condition for allowance, good cause has clearly been shown for the entry of these amendments. In any event, if nothing else, these amendments certainly reduce the number of issues presented by this application for the purposes of appeal. In addition, the total number of claims has not been increased, but has in fact been reduced. Reconsideration and allowance of the claims in this application are therefore respectfully solicited.

In the official action of June 12, 2006, all of the pending claims were rejected as being obvious over the combination of Hickie with Ujhelyi et al. In addition to the arguments which will now be presented in support of the patentability of the amended claims herein, also forwarded herewith is a declaration of Royce S. Fishman, one of the co-inventors in the present application. The enclosed declaration demonstrates that the inventors in the present application (Messrs. Fishman and Ujhelyi) made the presently claimed invention prior to the effective filing date of the Ujhelyi et al. '574 patent, and furthermore that the portions of the disclosure cited by the Examiner in this combination rejection from the Ujhelyi et al. '574 patent were actually learned by those patentees from the present applicants. Thus, for these reasons, it is clear that Ujhelyi et al. '574 is not

properly citable as a reference against this application. Without this linchpin to the combination rejection interposed by the Examiner, that rejection can no longer be made, and it is therefore clear that the present claims are patentable thereover. Even more particularly, however, the claims have also been amended to be directed to specific preferred embodiments of the present invention, most particularly in which nitrous-oxide-containing gases are specified in the claims for use in connection with the claimed methods hereof. Thus, applicants will also specifically and fully set forth the reasons why the present claims are clearly patentable over the prior art, even if it did include both Hickle and Ujhelyi et al., and for those further reasons should also be reconsidered and allowed at this time.

Claims 1-31 have been rejected as being unpatentable over Hickle in view of Ujhelyi et al. '574 under 35 U.S.C. § 103(a). The Examiner contends that Hickle discloses apparatus for relief from pain and anxiety associated with medical procedures including a care system 10, a drug delivery system 40, delivering gaseous sedative, analgesics or amnestic drugs in combination with oxygen gas, an electronic controller 14, and remote control device 45.

After admitting that Hickle does not disclose that the medical procedure is used for easing a patient's pain from atrial or ventricular defibrillation, Ujhelyi et al. '574 is relied upon. This reference is said to show, in pain controlling devices, that it is known to provide an inhalable gas to a patient from atrial or ventricular defibrillation, citing column 3, lines 64-67, and column 4, lines 1-16 thereof. It was thus said to be obvious to provide the medical gas of Hickle to a patient receiving atrial defibrillation, as taught by Ujhelyi et al. Based upon the capabilities of the controller and remote control devices of Hickle, it was said to be obvious

that with the remote information relating to atrial defibrillation, a third party can consider the information and assist the patient in inhaling the medical gas. The amount of gas given a user is said to be known based on knowledge of a doctor, and with respect to the limit of up to six minutes, the Examiner cites applicants' own disclosure in paragraphs [0169] and [0170] that the length of predetermined period of time between the beginning of gas administration and the FA-ICD shock depends on many factors, and therefore that length of time may depend on the nature and dose of the analgesic gas, or may vary from patient to patient. Thus, this limitation is said to be obvious based on applicants' own disclosure.

With respect to claim 2, it was said to be obvious to have the medical gas be one of the claimed gases as one would look to select a known gas to provide the analgesia or amnesia effects. With respect to claim 5, it was said to be an obvious design consideration to have the atrial device be an atrial fibrillation implantable cardioverter defibrillator as such devices are well known, it is said not to provide any advantage or solve any stated problem.

In response to applicants' prior arguments, applicants' own disclosure is again cited with respect to the specific time which is based on many factors which one would know to arrive at the claimed time ranges. This rejection is respectfully traversed in view of the above amendments and arguments, in light of the attached declaration, and for the reasons set forth hereinafter.

Turning to the Hickie reference itself, this patent discloses a large and complex apparatus for use in hospital facilities for relieving pain and anxiety during painful or anxiety-producing "medical or surgical procedures." A fair analysis of the disclosure in Hickie reveals that the care system, such as care system 10 shown in FIG. 1, does provide for

sedative, analgesic and/or amnestic drugs for a patient undergoing a medical or surgical procedure by a procedural physician. Thus, the housing 15 includes various storage compartments, including a drug delivery system 40 for delivering mixtures of one or more gaseous sedative, analgesic or amnestic drugs in combination with oxygen and/or other such drug delivery systems. The care system 10 also includes detailed microprocessor-based electronic controllers or computers within the housing so that during the continuing medical or surgical procedures themselves, the patient's vital signs can be monitored along with the patient's consciousness, comparisons can be made to safety data, and electronic controllers can manage application of the drug continuously to the patient while monitoring the patient's vital signs.

The present invention is not directed to any such system. Indeed, no device is intended to continuously apply any medical gases to a patient during an extended medical or surgical procedure itself. To the contrary, a short predetermined finite dosage of medical gas is provided for a patient to self administer the drug specifically in connection with atrial or ventricular defibrillation so that, even if the patient is far away from a hospital or medical facility, the patient can immediately deal with the associated pain and anxiety which is necessary in connection with the application of such defibrillation devices. Furthermore, this is precisely why the Examiner's disregarding of the significant claim limitation requiring use for up to six minutes, and reference to applicants' own disclosure in that regard, is so clearly improper. Admittedly, and as is spelled out in paragraphs [0169] and [0170], there are a number of factors which must be taken into account in selecting the precise short time period

which is utilized. The invention nevertheless requires a period of up to, but not more than, six minutes in order to constitute applicants' inventive contribution. As wrong as it is to use applicants' own invention against them (and it should be appreciated that applicants do not admit that these factors affecting the specific short period of time which is selected are part of the prior art), it is even more improper to therefore somehow conclude that a reference, Hickle, which is directed to a lengthy operative procedure, in any way suggests the method of the present invention, in which inhalation is entirely completed within a period of up to six minutes! This portion of the Examiner's position is simply without support.

In order to further demonstrate the significant patentable nature of the present claims over references such as Hickle, reference has also been previously made to an article by the applicants entitled "Nitrous Oxide Sedation Reduces Discomfort Caused by Atrial Defibrillation Shocks" or Ujhelyi et al., *Pacing and Clinical Electrophysiology*, Vol. 27, pgs. 485-91 (April 2004), a copy of which was previously submitted. This article relates in part to the applicants' own efforts to investigate the potentially significant nature of the concept underlying the present invention. In the Ujhelyi et al. article, reference is made to clinical testing which occurred to determine the efficacy of gases such as N₂O in mitigating atrial defibrillation shock-related anxiety, discomfort, and pain, as well as to evaluate patient acceptance of this treatment. Thus, patients with an implantable cardioverter/defibrillator having atrial therapies (ICT-AT) were utilized and the effect of N₂O-O₂ mixture treatment was evaluated. The results of this study demonstrate an important aspect of the significance of the present invention by establishing the impact of this method on anxiety, discomfort, and pain. In the tests which were thus

conducted, each of the patients received treatment with the N₂O mixture until either the patients stopped following verbal commands or four minutes of dosing had elapsed. The atrial shock was administered unless refused by the patient. The results dramatically demonstrated that in waking patients, this specific N₂O therapy significantly reduced shock-related anxiety, intensity, pain and discomfort by approximately 50-80%. The authors concluded that these results suggested that this type of N₂O therapy can be a safe and effective one to mitigate anxiety, pain and discomfort associated with ICD-AT atrial shocks, particularly as compared to the prior use of commonly used sedatives which incapacitated the patients for several hours. As stated in this article, "The principal benefit of the ICD-AT device is patient controlled defibrillation therapy for episodic AF without the need of a healthcare professional or facility." The subject matter of the claims of the present invention have, of course, now taken this conceptual data one step further, and actually demonstrated that this is truly the case. Compared to the system described in the Hickie reference, which is clearly limited to bedside use in a hospital, clinic or doctor's office, requiring the involvement of a medical professional, and which is not applicable to providing the benefits of the present invention, it is once again clear that the presently claimed invention provides a significant step forward in the art.

Applicants would next note that the Examiner has also applied these references to claim 9 and the claims dependent thereon. However, there is no reference whatsoever to ventricular defibrillation in Hickie, and there are only two passing references in Ujhelyi et al. '574; namely, at column 1, line 24, and column 4, line 10; but even in these cases, there is no specific teaching as to how one could use a method, such as that of the present invention, much less that of Ujhelyi

et al. itself, to deal with same. This reference is clearly directed to atrial defibrillation alone in all of its detailed disclosure. Indeed, ventricular fibrillation is a totally random event, in which the present invention now makes it possible to have the required analgesic, anxiolytic or anterograde amnesia agent available to the patient at any place and time for self medication immediately after the shock from the implantable cardioverter defibrillator or ICD device. The prior art provides no suggestion whatsoever of such a method.

Applicants would again emphasize, in connection with all of the claims pending in this application, that use of a predetermined short dosage (i.e. up to six minutes) device of the present invention, particularly as compared to the continuous flow of gases or other drugs as is the case in connection with Hickie, provides dramatically significant improvements in the results obtainable by patients utilizing this method.

Even apart from all of the above, and as has been previously pointed out, the Examiner has admitted that there are several clear deficiencies in Hickie, and has therefore found it necessary to combine this reference with Ujhelyi et al. Applicants previously pointed out that this patent was quite familiar to them, since Mr. Ujhelyi himself is a co-inventor of the present application. However, at this point, applicants would again refer to the enclosed Declaration of Mr. Fishman, demonstrating applicants' conception of the present invention prior to the filing date of Ujhelyi et al., as well as the disclosure by the applicants to that patentee of portions of Ujhelyi et al. referred to by the Examiner. Apart from all of the above, in any event, applicants are still of the opinion that the overall impact of the specific disclosures set forth in Hickie and Ujhelyi et al. do not in fact anticipate or obviate

the presently claimed invention. This is because, even with the portions of applicants' own disclosure, Ujhelyi et al. '574 itself is specifically directed to a patient's pain management system in which direct communication is obtained between an implanted device and an external drug delivery system so that upon arrhythmia an alert is provided which is communicated to the external drug delivery arrangement. Indeed, even in reference to nitrous oxide at column 4, line 32 of Ujhelyi et al., and even aside from the fact that this disclosure, as shown by the attached declaration, came from the inventors of the present application and is not citable as prior art hereagainst, it is clear from the use of this term in the context of the Ujhelyi et al. invention that this did not form part of their inventive contribution. Indeed, one of even minimal skill in this art would know that nitrous oxide alone could not be used for such purposes and would have disastrous effects. This is, in fact, the reason why the specific combinations of nitrous oxide with oxygen and/or other gases such as helium and nitrogen are set forth in claim 1, since these are specific gases which can actually be used in the method of the present invention, as opposed to nitrous oxide alone. Furthermore, the entire thrust of the disclosure in Ujhelyi et al. is directed to the use of an atrial defibrillation ICD device. Reference in this regard is thus made to claims, such as claim 9, which are specifically directed to ventricular defibrillation, now including the specific gases also set forth in claim 1, neither of which is shown in Hickie and/or in the prior art against this application. In addition, claim 13 is specifically directed to the use of a ventricular defibrillation implantable cardioverter defibrillator and/or an automatic external defibrillator in specific embodiments which are nowhere shown or suggested in this art. Additionally, new claims 32 and 33 are specifically directed to methods of using

these devices in the appropriate manner. None of this is shown or suggested even in Ujhelyi et al., even if it were fully citable hereagainst.

It is therefore respectfully submitted that each of the amended claims now set forth in this application clearly possesses the requisite novelty, utility and unobviousness to warrant their immediate allowance, and such action is therefore respectfully solicited. In any event, it is respectfully submitted, based on the contentions set forth above, that entry of these amendments is clearly warranted at this time, if nothing else but to place this application in better condition for purposes of appeal.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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